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| 10/018,821 | 06/09/2002 | Robert Short | H0664/7002 | 2143 |

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EXAMINER

NAFF, DAVID M

ART UNIT PAPER NUMBER

1651

DATE MAILED: 11/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,821

Applicant(s)

SHORT ET AL

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

A response of 9/19/05 presented arguments and did not amend the claims.

Claims examined on the merits are 1-32, which are all claims in
5 the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the
10 basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the
15 subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation
25 under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-4 and 6-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daw et al (C1 on form 1449) or France et al (C2 on form 1449) in view of Mayes et al (6,150,459) and McAuslan (WO 87/05038) (listed on form 1449) (both newly applied).

5 The claims are drawn to a therapeutic vehicle for use in tissue engineering comprising a cell culture surface having an acid functionality of at least 5% to which a cell can be reversibly attached. The cell culture surface can be prepared by plasma polymerization of acrylic acid or a copolymer of acrylic acid and 1,7-
10 octadiene to coat a substrate. The surface can have an acid functionality of 5-20% or greater than 20%. Also claimed is a method of preparing a cell culture surface of the therapeutic vehicle, and a method for treatment of cutaneous wounds using the therapeutic vehicle.

15 Daw et al and France et al disclose plasma polymerization of acrylic acid or plasma co-polymerization of acrylic acid and 1,7-octadiene on a substrate such as foil, or tissue culture wells or dishes to produce a surface containing acid functionality that binds cells and can be used for cell culture. The percent acid
20 functionality can be in the range of 5-20% or greater than 20%. For example, see Daw et al (page 1718, under "Experimental procedure"; paragraph bridging the columns and Figure 3 on page 1720; Figures 5 and 6 on page 1722; under "Discussion" on page 1723; and under "Conclusions" on page 1724). Also see France et al (paragraph
25 bridging pages 37 and 38; under "Cell attachment assay" and under

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"Characterisation of PCPs" and Table 1 on page 38; under "Discussion" on page 41; and under "conclusions" on page 42).

Mayes et al disclose coating the surface of a material with a copolymer, seeding the coating with cells, and implanting (col 16, lines 58-65) for tissue engineering (col 16, line 53). Also disclosed is wound-heating application (col 16, line 14).

McAuslan discloses forming an implant by applying to a substrate a hydrogel layer to which cells bind (page 5, lines 15-29).

It would have been obvious to apply the cell-binding polymer or copolymer of Daw et al or France et al to a substrate for implanting as suggested by Mayes et al and McAuslan applying a cell-binding polymer to a substrate to provide an implant, which can be seeded with cells. The resulting implantable substrate containing the cell binding polymer or copolymer of Daw et al or France et al is a therapeutic vehicle as presently claimed. The cell binding surface resulting from plasma polymerization as disclosed by Daw et al or France et al is the same as the cell culture surface of the therapeutic vehicle presently claimed, and contains an acid functionality as presently claimed.

Response to Arguments

Applicant's arguments filed 9/19/05 have been fully considered but they are not persuasive.

Applicants urge that Daw et al and France et al deposit the cell binding surface on foil, or tissue culture wells or dishes, which are not biocompatible and not inherently capable of implanting. However,

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in view of Mayes et al and McAuslan, it would have been obvious to deposit the cell binding surface of Daw et al or France et al on a substrate capable of being implanted. Daw et al and France et al bind to the cell binding surface osteoblasts and keratinocytes, respectively, that are cells normally used for implanting in tissue engineering. In regard to prior knowledge, Daw et al refer to tissue regeneration (page 1717, left col, under introduction) and France et al refer to the response of keratinocytes to natural and synthetic surfaces as of importance in wound care and healing (page 37, right col, first complete paragraph). This indicates that Daw et al and France et al considered a use of the cell binding surface to be tissue engineering, and the use of foil, or tissue culture wells or dishes was merely for *in vitro* testing to determine binding of cells to the surface.

Applicants urge that the specific vehicles of claim 32 are not disclosed by Daw et al and France et al. However, the vehicles include a matrix and polymeric film. The plasma polymer or copolymer disclosed by Daw et al and France et al is in the form of a film and is inherently a matrix. In any event, when using an implantable substrate as suggested by Mayes et al and McAuslan, the specific vehicles of claim 32 would have been obvious.

Claim Rejections - 35 USC § 103

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-4 and 6-32 above, and further in view of Yanagihara et al (4,693,799).

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whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
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DMN

11/19/05

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The claim requires propionic acid as the acid subjected to plasma polymerization to produce the cell culture surface.

Yanagihara et al disclose (col 6, lines 44-45 and line 58) producing a plasma polymerized film enriched in hydroxyl or carboxyl groups by plasma polymerizing an acid such as propionic acid.

When producing copolymer of Daw et al or France et al on an implantable substrate as set forth above, it would have been obvious to use propionic acid in place of the acrylic acid of Daw et al or France et al since Yanagihara et al suggest that propionic acid will provide the function of acrylic acid by disclosing plasma polymerization of propionic acid to produce a film containing carboxyl groups.

Response to Arguments

Applicants urge that Yanagihara et al is directed to improving lubricity of sliding surfaces, and one would not look to this reference. However, this reference like Daw et al and France et al is directed to producing a plasma polymerized film, and it would have been obvious for one having the Daw et al or France et al reference to look to any reference producing a plasma polymerized film. Applicants have established no unexpected result in using propionic acid in the plasma polymerization of the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff